

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT TACOMA

UNITED STATES OF AMERICA, *et al.*,

Plaintiffs,

*Ex rel.*,

JAMIE SIEGEL, M.D.,

Plaintiff-Relator,

v.

NOVO NORDISK, INC.,

Defendant.

CASE NO. D23-5459 BHS

ORDER

THIS MATTER is before the Court on defendant Novo Nordisk's (NNI's) *Daubert* motion to exclude the opinion testimony of plaintiffs<sup>1</sup> Jamie Siegel and Washington State's expert witness, Dr. Adriane Fugh-Berman. Dkt. 425.

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<sup>1</sup> This Order refers to plaintiff relator Siegel and intervenor plaintiff Washington State together as "Washington" for clarity, ease of reference, and consistency.

1 Fugh-Berman is a medical doctor who has spent her 35-year academic career  
2 researching how pharmaceutical companies market to the medical community, and how  
3 that marketing affects the prescription practices of that community. She has previously  
4 been qualified as an expert in this jurisdiction, and has testified about off-label  
5 promotion, sales and marketing tactics, and conflicts of interest in Continuing Medical  
6 Education (CME) before the FDA and Congress. She has authored and published per-  
7 reviewed articles. *See* Dkt. 449 at 2.

8 Fugh-Berman’s Report, Dkt. 387-1 at 342–389, opines broadly that NNI’s  
9 promotional methods and practices caused physicians and patients to use more  
10 NovoSeven, including off-label.

11 A qualified expert may testify in the form of an opinion or otherwise only if the  
12 proffered testimony is both relevant and reliable. Fed. R. Evid. 702; *Teradata Corp. v.*  
13 *SAP SE*, 124 F.4th 555, 566 (9th Cir. 2024) (citing *Daubert v. Merrell Dow*  
14 *Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)). Rule 702 and *Daubert* impose on the  
15 district court a “gatekeeping” duty to ensure that opinion testimony is relevant and  
16 reliable, and an expert’s opinion should be excluded if it does not have a reliable  
17 foundation or if it is not based in the knowledge and experience of the relevant discipline.  
18 *Sonneveldt v. Mazda Motor of Am., Inc.*, 2024 U.S. App. Lexis 32836, \*3 (9th Cir. Oct.  
19 21, 2024) (citing *Primiano v. Cook*, 598 F.3d 558, 564-65 (9th Cir. 2010)). “Expert  
20 opinion testimony is relevant if the knowledge underlying it has a valid connection to the  
21 pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in  
22 the knowledge and experience of the relevant discipline.” *Surgical Instrument Serv. Co.*

1 *v. Intuitive Surgical, Inc.*, 2024 U.S. Dist. Lexis 81690, \*5 (N.D. Cal. March 31, 2024)  
2 (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 739 F.3d 960, 969 (9th Cir.  
3 2013)). When an expert meets the Rule 702 threshold the expert may testify, and the jury  
4 decides how much weight to give that testimony.” *Primiano*, 598 F.3d at 565.

5 NNI does not directly challenge Fugh-Berman’s credentials, and it does not argue  
6 that she is not an expert in her field. It does emphasize that she self-identifies as an  
7 “activist” advocating for “rational prescribing and promoting public health,” and that her  
8 opinions have been excluded as irrelevant in other cases. Dkt. 425 at 6 (citing *In re*  
9 *Prempro Prods. Liab. Litig.*, 2012 WL 12906583, at \*3 (E.D. Ark. Aug. 29, 2012), and  
10 *Baldonado v. Wyeth*, 2012 WL 1802066, at \*4 (N.D. Ill. May 17, 2012)).

11 NNI seeks to exclude Fugh-Berman’s opinions, arguing that she fails to set out  
12 sufficient facts and data to support her unreliable analytical methodologies, and fails to  
13 reliably apply her principles and methods. *Id.* at 9. It further argues that her testimony is  
14 not relevant and that, though she may be an expert, her expertise does not extend to the  
15 clinical or regulatory issues in this case. *Id.* at 22.

16 NNI specifically challenges Fugh-Berman’s reliance on “discourse analysis” to  
17 support her conclusion that NNI’s promotional activities improperly affected prescribing  
18 physicians’ judgment when selecting a pharmaceutical to treat a hemophilia patient. NNI  
19 argues persuasively that discourse analysis was not even mentioned in her Report. *Id.* at  
20 13. Indeed, absent NNI’s description of “discourse analysis” and its use, the Court would  
21 have little understanding of the concept, and how it can be used to demonstrate improper  
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1 or illegal influence upon prescribing physicians. The Court therefore precludes any  
2 opinion testimony about applying “discourse analysis” unless raised by the defense.

3 Fugh-Berman has general knowledge from experience and known studies and is  
4 qualified to testify generally about physician behavior in prescribing pharmaceuticals,  
5 and what can influence that behavior. However, she will not be permitted to testify that  
6 NNI’s promotional methods were responsible for “specific increases in the prescribing  
7 behavior” of Patient A’s primary physician, Dr. Louie, or about the effects of the  
8 promotions on Patient A. NNI persuasively argues that Fugh-Berman did not review  
9 specific “claims data” and “medical records” associated with Patient A’s use of  
10 NovoSeven. *Id.* at 10.

11 Fugh-Berman may summarize what benefits the record demonstrates were  
12 provided to Dr. Louie and Patient A that may have influenced Dr. Louie in the way that  
13 studies have shown that these types of benefits influence prescription choices. She will  
14 not be permitted to testify that these benefits caused Dr. Louie to use NovoSeven. This is  
15 an ultimate legal conclusion for the jury.

16 Dr. Fugh-Berman will be permitted to express the opinions summarized as  
17 opinions “A” and “B” in her Report, Dkt. 387-1 at 344. She is precluded from expressing  
18 opinion “C,” beyond summarizing the benefits the record shows Dr. Louie, Patient A,  
19 and his mother received, and opine that they are the sorts of benefits that studies show  
20 influence physicians’ prescribing behavior. The remainder of opinion “C” is  
21 impermissible argument. It also includes an opinion characterizing the off-label, high  
22 dosage use of NovoSeven as “unproven,” an opinion she is not qualified to give.

1 Similarly, Fugh-Berman may not testify as to opinions “D” (“Payments, gifts and  
2 services provided to physicians and patients influenced prescriptions written for  
3 NovoSeven”) and “E” (“Influence on physicians and patients was a major cause of and  
4 substantially contributed to off-label use.”). *See* Dkt. 387-1 at 345. These are  
5 impermissible ultimate legal conclusions.

6 NNI also objects to Fugh-Berman’s proposed “factual narrative” testimony. It  
7 argues, persuasively, that it would be improper for her to offer a speculative editorial  
8 about the alleged nefarious global effects of [NNI’s] marketing practices” and its “sway  
9 over the medical community” because it is “neither relevant nor reliable.” Dkt. 425 at 6  
10 (quoting *Baldonado*, 2012 WL 1802066, at \*4 (excluding Fugh-Berman’s testimony)).

11 The Court agrees that no expert shall testify in a form of an advocate  
12 editorializing, or present a conclusory narrative akin to attorney argument, rather than as  
13 an expert witness.

14 Fugh-Berman’s Report concludes with two paragraphs opining about the purpose  
15 and effect of NNI’s allegedly illegal marketing tactics, and specifically about the  
16 consequences of the benefits it provided to Dr. Louie, Patient A, and his mother. Dkt.  
17 387-1 at 389. These ultimate conclusions of law are for the jury, and she will not be  
18 permitted to so opine. She cannot characterize the high dosage or prophylaxis use of  
19 NovoSeven as “unproven.” She can testify that, generally, based on her experience,  
20 scholarship, and training, promotional campaigns have been shown to affect such  
21 behavior.  
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1 And, like any expert, Fugh-Berman can rely on the expert opinions of other  
2 experts as a foundation for the opinions within the expert's field of expertise. *Villagomes*  
3 *v. Lab. Corp. of Am.*, No. 2:08-cv-00387-RLH-GWF, 2010 WL 4628085, at \*4 (D.Nev.  
4 Nov. 8, 2010); Fed. R. Evid. 702 Committee Notes on Rules—2000 Amendment (“The  
5 term ‘data’ in Rule 702 is intended to encompass the reliable opinions of other experts.”).

6 Fugh-Berman has the training, education and experience to opine about the topics  
7 in her Report, as limited by this Order. She is a qualified and she has used reliable  
8 principles and methods with sufficient facts to support those opinions. Her testimony will  
9 assist the jury in understanding the evidence in the case or determine a fact in issue.

10 NNI's *Daubert* motion to exclude Fugh-Berman's testimony, Dkt. 425, is  
11 **GRANTED** in part and **DENIED** in part.

12 **IT IS SO ORDERED.**

13 Dated this 16th day of July, 2025.

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16 BENJAMIN H. SETTLE  
17 United States District Judge  
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